2018 Current Fiscal Year Report: Risk Communication Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Risk Communication Advisory Committee	31951

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/17/2009		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 360bbb-6	09/27/2007	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
The committee discussed the impact of pregnancy and lactation labeling information in prescription drug and biological products as modified under the Pregnancy and Lactation Labeling Rule. The Pregnancy and Lactation Labeling Rule (PLLR) was implemented in June 2015, and required changes to labeling of information in prescription drug and biological products to better communicate clinically relevant information to health care providers on risks associated with medication exposure during pregnancy and lactation. The Agency seeks input and recommendations on: (1) How information in PLLR labeling is being perceived and used by health care providers and other stakeholders, (2) factors that are critical to health care providers' interpretation of the data and counseling of pregnant women on the risks and benefits of a medication, and (3) how to convey risk information to health care providers to accurately and adequately inform risk-benefit considerations for medication use during pregnancy.	03/05/2018	03/06/2018

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$17,693.00	$16,304.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$347,080.00	$354,768.00
18a(4). Personnel Pmts to Non-Member Consultants	$15,965.00	$17,000.00

18b(1). Travel and Per Diem to Non-Federal Members	$15,199.00	$30,931.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$90,703.00	$96,715.00
18d. Total	$486,640.00	$515,718.00
19. Federal Staff Support Years (FTE)	2.35	2.35

20a. How does the Committee accomplish its purpose?

The RCAC meets up to four times per year. Members' comments and discussion provide advice to the Agency on improving communications practices, from both a basis of scientific research and practical experience, in matters ranging from specific types of agency communications to more general strategies and research needs, in order to help the agency accomplish its goal of improving patient and consumer safety by providing risk-benefit information that is clear, timely, and usable by the audience. The meetings also facilitate the RCAC purpose of interactive sharing of information between the FDA and the public.

20b. How does the Committee balance its membership?

The RCAC consists of 15 voting members including the Chair. Members are selected among authorities in fields such as risk communication, social marketing, health literacy, and other relevant areas. Some members will be selected to provide experiential insight on the communications needs of various groups who use FDA-regulated products such as patients, healthcare professionals, consumer or patient advocacy organizations. Depending on the topic, the commissioner or designee may select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. FDA will give close attention to distribution with respect to members' geographic region, minority status, and sex, so long as the effectiveness of the Committee is not impaired.

20c. How frequent and relevant are the Committee Meetings?

Approximately 2 meetings per year are projected; 1 meeting was held in the current fiscal year.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

FDA strives to communicate with many audiences using many instruments, but in the past not all were developed or evaluated in ways consistent with established best practices in risk communication. The RCAC is necessary in order to bring expertise on current

research and established best practices to the Agency, to help the agency interact with the public for more effective risk communication. This need was recognized both in the Congress (HR 3580) and the National Academies' Institute of Medicine (The Future of Drug Safety, recommendation 6.1).

20e. Why is it necessary to close and/or partially closed committee meetings?

There were no closed meetings to report in FY-18.

21. Remarks

In FY-18, the RCAC held one meeting, March 5-6, 2018. The committee met to discuss the impact of pregnancy and lactation labeling information in prescription drug and biological products as modified under the Pregnancy and Lactation Labeling Rule. The Pregnancy and Lactation Labeling Rule was implemented in June 2015, and required changes to labeling of information in prescription drug and biological products to better communicate clinically relevant information to health care providers on risks associated with medication exposure during pregnancy and lactation.

Designated Federal Officer

Russell T. Fortney DFO

Committee Members	Start	End	Occupation	Member Designation
Baur, Cynthia	10/01/2017	09/30/2021	Endowed Chair and Director, Horowitz Center for Health Literacy, School of Public Health, University of Maryland	Special Government Employee (SGE) Member
Berube, David	10/01/2016	09/30/2020	Professor, North Carolina State University	Special Government Employee (SGE) Member
Blalock, Susan	10/01/2013	09/30/2018	Professor of Pharmacy, University of North Carolina	Special Government Employee (SGE) Member
Capella, Joseph	10/01/2017	09/30/2021	Gerald R. Miller Professor of Communication, Annenberg School for Communication, University of Pennsylvania	Special Government Employee (SGE) Member
Coombs, W. Timothy	10/01/2017	09/30/2021	Professor, Department of Communication, Texas A&M University	Special Government Employee (SGE) Member
Dieckmann, Nathan	10/01/2017	09/30/2021	Research Associate Professor, School of Nursing, Oregon Health and Science University	Special Government Employee (SGE) Member
Dillard, James	12/31/2015	09/30/2019	Professor of Communication Arts and Sciences, Penn State University	Special Government Employee (SGE) Member
Howlett, Elizabeth	10/01/2017	09/30/2021	Professor, Department of Marketing & International Business, Carson College of Business, Washington State University	Special Government Employee (SGE) Member
Kreps, Gary	10/01/2017	09/30/2020	Professor, George Mason University	Special Government Employee (SGE) Member
Lee, Charles	10/01/2014	09/30/2018	founder and President, Polyglot Systems, Inc.	Special Government Employee (SGE) Member
Pleasant, Andrew	10/01/2014	09/30/2018	Senior Director, Canyon Ranch Institute	Special Government Employee (SGE) Member
Rimal, Rajiv	12/31/2015	09/30/2019	Professor and Chair; George Washington University	Special Government Employee (SGE) Member
Sneed, Jeannine	12/31/2015	09/30/2019	Sneed Consulting	Special Government Employee (SGE) Member
Wolf, Michael	10/01/2017	09/30/2020	Professor, Northwestern University	Special Government Employee (SGE) Member

Zavala, Mirian	10/01/2014	09/30/2018	Assistant Professor, Nursing, College of Mount Saint Vincent, Bronx, NY	Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Risk Communication Advisory Committee supports FDA's strategic priorities by providing expert advice on FDA strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products, review and evaluate scientific research relevant to risk communication, and facilitate the interactive sharing between FDA and the public of information on risks and benefits of FDA-regulated products.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	

$100,000 - $500,000 ☐
$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
The utilization of the Risk Communication Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical, scientific and communications experts not otherwise available to the Agency and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
188

Number of Recommendations Comments
The committee made 188 recommendations from FY03 through FY18, following the convention 1 topic = 1 recommendation

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
20%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
70%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA

most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

Feedback is usually provided. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The committee does not advise on resource allocation, but prioritization may be reflected in resource allocation. The other actions boxes above that are checked applicable are showing that the Agency is actively engaged in developing internal strategy, process, and capacity to implement recommendations more fully, but none of this is complete at this time. The boxes above that are blank are, to date, inapplicable.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑

Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A